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10/665,793	09/19/2003	Edward J. Kaplan	KAP 100 CIP	6738

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EXAMINER	
SAMALA, JAGADISHWAR RAO	
ART UNIT	PAPER NUMBER
1618	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/665,793	KAPLAN, EDWARD J.	
	Examiner	Art Unit	
	JAGADISHWAR R. SAMALA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36-46 and 48-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36-46 and 48-70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/02/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Applicant's Amendments and Request for Continued Examination filed on 03/02/2009.

Claims 36, 47 and 48 have been amended.

Claim 47 has been cancelled.

Claims 56-70 have been added.

Claims 36-46 and 48-70 are pending in the instant application.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/02/2009 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 36-46 and 48-70 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new mater rejection.

Claims 36-47 and 48-70 recite the newly amended limitation of one or more structures effective to prevent migration or maintain orientation in tissue are selected from group consisting of "studs, knobs, ribs, fins, bristles, bands, hooks, braids", however, the specification as filed does not provide a written description or set forth the metes and bounds of this phrases. The instant claims also recites "one or more structures prevents migration of the seed for a period of time from about 10 minutes to about three years", however, the specification as-filed does not provide a written description or set forth the metes and bounds of this phrases. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, introduce new concepts and thus violate the written description requirement of the first paragraph of 35 U.S.C. § 112.

Claims 64-66 recite the seed is in "a magazine or cartridge", however, the specification as-filed does not provide a written description or set forth the metes and bounds of this phrases. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, introduce new concepts and thus violate the written description requirement of the first paragraph of 35 U.S.C. § 112.

Applicant is required to cancel the new matter in the response to this office action. Alternatively, Applicant is invited to identify sufficient written support in the original specification for the "limitations" indicated above.

4. Claims 36-46 and 48-70 are rejected under 35 U.S.C. 112, first paragraph, because specification, while being enabling for a seed to implant into a target tissue and trace the orientation of the seed, dose not reasonably provide enablement for preventing migration of the seed for a period of time from about 10 minutes to about three years. The specification does not enable any person skilled in the art to which it pertains, or with which it is mot nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir.1988). Among these factors are: 1) scope of breadth of the claims; 2) nature of the invention; 3) relative level of skill possessed by one of ordinary skill in the art; 4) state of, or the amount of knowledge in, the prior art; 5) level or degree of predictability, or a lack thereof, in the art; 6) amount of guidance or direction provided by the inventor; 7) presence or absence of working examples; and 8) quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

1) Scope or breadth of the claims: The claim is broader in scope than the enabling disclosure. The specification discloses, without more, to prevent migration of the seed for a long period of time in various targeted tissues in a subject. However, Applicant is purporting to prevent migration of seed.

2) Nature of the invention: The nature of the invention is directed to a seed, for implantation into a target tissue and seed having one or more structures to maintain and trace the orientation of the seed in a subject.

3) Relative level of skill possessed by one of ordinary skill in the art: The relative level of skill possessed by one of ordinary skill in the art of medical research is relatively high, as a majority of lead investigators conducting scientific research and development in this particular area posses M.D. and/or Ph.D. in a scientific discipline such as medicinal chemistry, biochemistry, pharmacology, biology or the like.

4 State of, or the amount of knowledge in the prior art: The art teaches implantation of brachytherapy seeds using permanent stranded seeds and seeds are spaced at a fixed distance within absorbable material. Strand technique is often employed to improve seed spacing and to inhibit seed migration. And also art teaches improved treatment of medical conditions such as neoplastic diseases according to the normal practice of brachytherapy, e.g., the interstitial implantation of radioactive sources into tumorous tissue for the purpose of irradiating and thus killing malignant cells (US 5,713,828).

5) Level or degree of predictability, or lack thereof, in the art: A high degree of unpredictability existed in the state of the prior art regarding how to prevent migration

of implanted seeds into tumorous tissue for the purpose of irradiating the tumors. Many risk factors cannot be controlled to prevent migration of the seed for longer period of time. The permanent seed implantation has been used to treat various types of cancers, such as pancreas, liver, lung and others. For example, a successful technique for delivering radioactive seeds to the prostate for treatment of cancer therein, a plurality of elongated needles, each loaded with a series of radioactive seeds, are inserted through the perineum area of the patient into the prostate. However, when the needle is removed from the prostate, seeds can migrate to area within and without the prostate after the needle has been removed. Also, if the needle is removed too fast, the seeds may be drawn in the direction of the needle removal line, due to a vacuum-like effect which occurs when the needle is withdrawn. A change from the intended position of the individual radioactive seeds in the prostate will result in a change of the radiation dosimetry within the prostate, which is undesirable. Further, to prevent migration of the seeds it would widely depend on the size of the seed, size of studs, or knobs, or hooks etc on the seed and most importantly the organ systems or tissues that are not amenable to this type of permanent seed implantation.

6. Amount of guidance or direction provided by the inventor: Applicant was required to provide in the specification additional guidance and directions with respect to how to use the claimed subject matter in order for the claim to be enabled with regard to the full scope of the claimed invention. Although, the instant specification discloses a material suitable for implantation in a target tissue in an animal subject that can be associated with therapeutically active component such that all or part of the

therapeutically active component will be delivered to the target tissue when the brachytherapy strand is introduced into the implantation site, and a means for readily imaging implanted seeds, the specification also discloses that the built-in-ridges, bumps, and related structures can ameliorate seed migration problem to some extent, but will not completely eliminate it (instant specification, page 37 lines 20-24). Thus, by Applicant's own disclosure, the instant claimed seed, for implantation cannot prevent migration of the seed for a long period of time in various targeted tissues in a subject.

7) Presence or absence of working examples: The specification fails to provide scientific data and working embodiments with respect to prevention of migration of the seed for a long period of time in various targeted tissues in a subject.

8) Quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure: As a result, one of ordinary skill in the art would be required to conduct an undue amount of experimentation, to reasonably and accurately determine whether the composition and corresponding seed of the instant application does in fact prevent migration of the seed for a long period of time in various targeted tissues in a subject.

In conclusion, it is readily apparent from the aforementioned disclosure, in conjunction with the lack of scientific data and working embodiments regarding the prevention of migration of seed, one of ordinary skill in the art would therefore be required to conduct an undue amount of experimentation to reasonably and accurately extrapolate whether said seed upon implantation would prevent migration of the seed for a long period of time in various targeted tissues in a subject.

Claim Rejections - 35 USC § 103

Claims 36-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zamora et al. (US 2001/0044567 A1) and Grimm (US 6,010,446) in view of Coniglione (US 5,713,828) **are withdrawn**.

However, upon further consideration, a new ground(s) of rejection is made as discussed below.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 36-46 and 48-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zamora et al (US 20010044567) in view of Sioshansi et al (US 6,419,621), Grimm (US 6,010,446) and Reed et al (IS 2002/0058854 A1).

Applicant claims are drawn to a seed for implantation into a subject, wherein the seed is a combination product comprising: a biocompatible carrier, one or more therapeutic components, an imaging, radiopaque , or other diagnostic marker, and one

or more structures to prevent migration of the seed for a period of time from about 10 minutes to about three years.

Zamora discloses a brachytherapy device comprising a biocompatible biodegradable component (i.e. polymeric material), a non-radioactively therapeutic component and a biodegradable radiopaque marker (see abstract). The biodegradable component includes polymers (e.g. Poly (D,L-lactide) poly (L-lactide, (polyglycolide, poly (L-lactide-co-glycolide) that are same as those claimed (0025 and 0055). The biocompatible polymer such as poly (hydroxybutyrate) is included that can read as biocompatible elastic Carrier to form an elastic brachytheraphy seed (0049) since they are essential same compounds. The size and shape of the seeds are within the scope of those claimed (0057+). The outer surface of device have sufficient permanence or persistence so that the radioactive source material remains localized at the site of implantation at all times for use in treatment of diseases, including radiation therapy of cancers (0029 and 0031). Metallic elements with suitable biocompatibility and radiocapacity include titanium, zirconium, tantalum barium, bismuth and platinum (would read on trace is fluorescent, 0051).The non-radioactive therapeutic component includes chemotherapeutic agent such as cisplatin bleomycin, a radiosensitizer drug such as 5-halo uracil compounds and plasma coating, such as siloxane (which would read on inorganic substance) to modulate or control the bioabsorption rate of the radiopaque medium (0080). Zamora also teaches the radiopaque marker which includes various markers that are biodegradable such as platinum, tantalum and bismuth (0051), where these markers are same as one required by claims, thus non-radionuclide imaging

marker requirement is inherently met. The seeds of the device may be implanted singly, or may utilize suture strands (chains), webs, meshes or other means to group the devices in a desired manner (0085+). Additional disclosure includes, that the improved delivery devices deliver local radiation, and optionally local chemotherapeutic or bioactive drugs, and are degradable after implantation so that the devices largely or completely disappear from the treatment region over time.

Zamora fails to disclose one or more biodegradable structures to prevent migration of the seed, a spacer element for use in between radioactive seeds and a seed is in a magazine or cartridge.

Sioshansi discloses a brachytherapy device in the form of a radioactive flexible coiled wire and a delivery vehicle for inserting the elongated element into the patient at or near the treatment site (abstract and col. 9 lines 60+). The radioactive coils can be cut into desired lengths to form seed-like brachytherapy structures. The device can include one or more anchoring structures of various forms known in the art for fixation of the device in the host tissue so that it remains in place after implantation for the duration of the radiation treatment, and possibly indefinitely (col. 10 lines 12-40).

Grimm discloses a spacer element for use between radioactive seeds in needle implant treatment for prostate cancer, comprising: a spacer element having a center section and two end sections, the two end sections being configured, respectively, to hold an adjacent radioactive seed such that a spaced plurality of radioactive seeds results from the connection of successive spacers and seeds; wherein the spacer element is made from a material which is absorbable in living tissue; and wherein a

combination of spacer element and radioactive seeds can be fitted within a needle for subsequent insertion into the prostate treatment thereof (abstract and col. 1 lines 65+). The presence of the spacer elements, physically linking adjacent radioactive seeds, will substantially prevent any migration of the individual seeds following the desired placement thereof within the prostate, either from the action of removing the needle or normal tissue movement within the prostate. This arrangement thus maintains, almost perfectly, the planned radiation dosimetry pattern for the patient, which is an extremely important objective and thus substantially solves the seed migration problem (col. 3 lines 33-43).

Schmidt discloses a disposable brachytherapy device includes an applicator, having a transparent plastic cartridge, for holding a plurality of radioactive tumor-killing seeds (abstract).

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate brachytherapy seeds having one or more biodegradable structures to prevent migration of seeds upon implantation into a target tissue disclosed by Zamora. The person of ordinary skill in the art would have been motivated to make these modification because radioactive seeds having one or more anchoring structures of various forms would prevent migration of seeds upon implantation and reliably, without risk that the radiation source will migrate become dislodged from its intended position and reasonably would have expected success because it is well known in the art that the anchoring structures of various forms for fixation of the device in the host

tissue so that it remains in place after implantation for the duration of the radiation treatment, and possibly indefinitely.

It would have been obvious to one of ordinary skill in the art at the time of the invention was made to incorporate a spacer material attached to the seed and a seed cartridge to hold radioactive seed as disclosed by Zamora. The person of ordinary skill in the art would have been motivated to make these medications because the presence of the spacer elements, physically linking adjacent radioactive seeds, will substantially prevent any migration of the individual seeds following the desired placement thereof within the target tissue and reasonably would have expected success because physically linking radioactive seeds via spaces maintains almost perfectly, the planned radiation dosimetry pattern for the patient.

Response to Arguments

Applicant's arguments filed on 03/09/3009 have been fully considered but they are not persuasive.

Applicant asserts that Zamora does not disclose or suggest structures attached to the seed to maintain its position and/or orientation as required by the claims.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combination of references. See in re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981): In re Merck & Co., 800 F.2d 1091,231 USPA 375 (Fed.Cir.1986).

In this case, the Zamora patent is relied upon to show that it is known in the art to manufacture radioactive seeds for interstitial radiotherapy of malignant neoplasms or

other diseases treatable with radiation. Zamora discloses method and improved delivery devices to deliver local radiation, and chemotherapeutic or bioactive drugs, and after implantation so that the radioactive source material localized at the site of implantation at all times while emitted radiation remains significant (0029). The outer surface of devices, however, have sufficient permanence or persistence so that the radioactive source material remains localized at the site of implantation at all times while the emitted radiation remains significant .The brachytherapy devices disclosed by Zamora are made such that the density of the device approximates that of normal and cancerous tissues or frequently have a greater density than that of the tissue within which they are placed. By approximating the density of the tissue in which the devices are placed, movement of the devices within the body is minimized (see para 0083). And thus, the device disclosed by Zamora would obviously retain integrity throughout the period of active emission of radiation.

Applicant also asserts that Zamora does not disclose a degradable radiopaque marker.

This argument is not persuasive since, Zamora does disclose radiopaque material capable of being detected by X-rays and conventional radiographic methods. Preferred iodine-containing radiopaque agents include iodixanol, iohexol, iodophthalein sodium, and metal containing contrast agents such as barium sulfate and bismuth trioxide, which can be mixed with polymers such as polyurethane to increase radiocapacity and the like (see para 0051).

Applicant also asserts that Grimm does not disclose or suggest one or more biodegradable structures on the surface of the seed or spacer, effective to prevent migration of the seed into a target tissue.

This argument is not persuasive since this reference is combined for its teachings of knowledge in the art of attaching radioactive seeds and spacer element is also configured to fit within a conventional needle which is loaded with an alternating succession of radioactive seeds and spacer elements, for subsequent positioning in the prostate.

Applicant also asserts about "Long Standing Need and Commercial Success" of the seeds.

The relevance of long-felt need and the failure of others to the issue of obviousness depend on several factors. First, the need must have been a persistent one that was recognized by those of ordinary skill in the art. In re Gershon, 372 F.2d 535, 152 USPQ 602,605 (CCPA 1967). The alleged problem in this case is migration of seeds from the implantation site, and the prior art also discloses the brachytherapy devices capable of retaining integrity throughout the period of active emission of radiation (i.e., minimizes the chance of migration of implanted seeds within a patient's body). And further, the invention must in fact satisfy the long-standing need. In re Cavanagh, 436 F.2d 491,168 USPQ (CCPA 1971).

Objective evidence of nonobviousness including commercial success must be commensurate in scope with the claims. In re Tiiffin, 448 F.2d 791,171 USPQ 294 (CCPA 1971). In order to be commensurate in scope with the claims, the commercial

success must be claimed features, and not due to unclaimed features. Joy Technologies Inc. v. Manbeck, 751 F. Supp.225, 229, 17 USPQ2d 1257, 1260 (D.D.C. 1990), aft'd, 959 F.2d 226,228, 22 USPQ2d 1153, 1156 (Fed. Cir. 1992)

The instant claim 36, a seed for implantation into a subject, wherein the seed is a combination product comprising a biocompatible carrier, one or more therapeutic components, an imaging, radiopaque, or diagnostic marker, and one or more structures to maintain location or orientation of the seed upon implantation. The claim does not say anything about anchor seed and the feature recited in the commercial success product is for anchorseed designed to help reduce seed misalignment and seed migration. The examiner does not know the composition of the anchorseed and also to compare it with the instant claims.

An affidavit or declaration attributing commercial success to a product or process "constructed according to the disclosure and claims of [the] patent application" or other equivalent language does not establish a nexus between the claimed invention and the commercial success because there is no evidence that the product or process which has been sold corresponds to the claimed invention, or that whatever commercial success may have occurred is attributable to the product or process defined by the claims. Ex parte Standish, 10 USPQ2d 1454, 1458 (Bd. Pat. App. & inter. 1988). Furthermore, the success of an embodiment within the claims may not be attributable to improvements or modifications made by others. In re Vamco Machine & Tools, Inc., 752 F.2d 1564, 224 USPQ 617 (Fed. Cir. 1985).

Double Patenting

Claims 36-40, 45, 47-55 are rejected on the ground of nonstatutory obviousness type double patenting as being unpatentable over claims 1-3, 5,10,12,13, 30, 32, 35, 38 and 41 of US 6,746,661 B2 **are maintained** for reasons of record in the previous office action filed on 09/30/3008.

Applicant asserts that brachytherapy seeds formed of biodegradable polymer have elastic properties and other distinct structures for maintaining the location of the seed.

This argument is not found persuasive since the polymers used in the instant claims and polymers disclosed in US 6,746,661 are biodegradable polymers and would have the elastic properties. And further, the US 6,746,661 is silent about the migration of seeds from the implantation site (for maintaining the location of the seed). Thus, the instant claim is within the scope of the claim of the US Pat. 6,746,661. Thus scope is overlapping each other and properly included in the rejection because they are patentably distinct from each other. Thus, the claim is readily envisaged by the teaching of the prior art and the claim is properly included in the rejection. Accordingly, ODP is maintained.

Conclusion

1. No claims are allowed at this time.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Examiner, Art Unit 1618

Jagadishwar R Samala
Examiner
Art Unit 1618

sjr